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GOVERNMENT OF SIKKIM
DEPARTMENT OF HEALTH CARE, HUMAN SERVICE & FAMILY WELFARE
GANGTOK

No. 04/HC.HS & F.W **Dated: 10.2.2005.**

NOTIFICATION

Whereas the State Government had published the Sikkim Clinical Establishments (Licensing and registration) Rules, 1996, under the Notification of Health and Family Welfare No. 10/MH&FW, dated 3.03.1997, published in the Sikkim Government Gazette Extraordinary number 56 dated the 28th April, 1997;

And whereas the State Government now proposes to amend certain provisions of the Sikkim Clinical Establishments (Licensing and Registration) Rules, 1996 which is hereby published as required by sub-section (1) of section 19 of the Sikkim Clinical Establishments (Licensing and Registration) Act, 1995, for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will be taken into consideration on or before 45 (forty five) days from the date of publication in the Official Gazette;

Any objection or suggestion that may be received from any person with respect to the said draft rules before the expiry of the period so prescribed shall be taken into consideration by the State Government;

Now, therefore, in exercise of the powers conferred by sub-section (2) of section 19 of the Sikkim Clinical Establishments (Licensing and Registration) Act, 1995, the State Government hereby makes the following rules to amend the Sikkim Clinical Establishments (Licensing and Registration) Rules, 1996 namely:-

DRAFT RULES

Short title and commencement.

1. (1) These rules may be called the Sikkim Clinical Establishments(Licensing and Registration) Amendment Rules, 2004.

(2) They shall come into force on such date as the State Government may, by notification in the Official Gazette, appoint.

Amendment of Rule 7.

2. In the Sikkim Clinical Establishments (Licensing and Registration) Rules, 1996, (hereinafter referred to as the said rules), for the existing rule 7, the following shall be substituted, namely:-

"7.(1) The fees to be paid for registration and renewal of registration shall be Rs.1000/- (Rupees one thousand only) for all types of Clinical Establishments as defined under clause (b) of section 2 of the Act.

The renewal of registration is to be done every five years.

(2) The license fee and renewal of license fee shall be charged at the rate of Rs. 5000/- (Rupees five thousand only) for all types of Clinical Establishments as

defined under clause (b) of section 2 of the Act, except those with the provision of beds for the patients where a sum of Rs. 5000/- (Rupees five thousand only) shall be charged with 10 (Ten) number of beds or less and an addition of Rs.1000/- (Rupees one thousand only) shall be charged for every increment of 10 beds.

The license shall be renewed annually."

Amendment to 3. Schedule. In the said rules, in the Schedule, after sub-paragraph (i) of Paragraph 7, the following shall be inserted, namely:-

"8. (1) An establishment of Pathology Laboratory shall fulfil the following criteria:

(a) Location and Surroundings
The Diagnostic Laboratory shall be situated in a place having clean surroundings and shall not be adjacent to an open sewer or public lavatory. Proper attention must be given to the size of the premises, fittings and furnishings, work surfaces, the flooring of the laboratory, the lighting, ventilation and storage facilities.

(b) Small laboratory
A laboratory performing routine tests in hematology, clinical pathology and biochemistry up to fifty tests per day by manual or semiautomatic techniques.

(c) Medium laboratory
A laboratory performing routine tests in hematology, clinical pathology and biochemistry or other laboratory disciplines (such as histopathology, cytopathology) and doing fifty one to five hundred tests per day.

(d) Large laboratory
A laboratory performing the above mentioned tests higher than five hundred tests per day and or using sophisticated instruments such as automated analyzer,ELISA readers, fluorescent microscopes, etc.

(e) Super Specialty laboratory
A laboratory restricting its activity to one or two disciplines of laboratory medicine.

(2) **Staff and Qualification**
(a) Supervisory Personnel
The large and super specialty laboratory shall be supervised by a person with post-graduate qualification in pathology or microbiology or biochemistry or Ph.D. in the respective discipline. The small and medium laboratory may be manned by an MBBS or a M.Sc. with atleast five years of experience in laboratory medicine.

(b) Technical Personnel
The technical person performing the tests should have the following qualification:-

- Graduate in Medical Laboratory Technology, or
- Diploma in Medical Laboratory Technology (2 years course) awarded by a University or State Government or Central Technical Board.

The laboratory shall have a system of imparting training to technical staff at various levels. There shall be a system so that a technical person receives adequate training in the operation of new analytical equipments and performances of new test before he/she is assigned to such work.

(c) Space and Accommodation
The minimum space required to run a diagnostic laboratory should be 200 square feet. Separate space should be available for sample collection and to store chemicals. For

medium and large laboratories and super specialty laboratories the minimum space should be 300 square feet. Separate space should be available for various branches of laboratory medicine.

(d) Safety programme

The diagnostic laboratory can be a hazardous workplace unless proper precautions are taken.

The laboratory safety programme should include establishment of a safety policy and proper disposal of waste and related material as per guidelines implemented by the State Government from to time to time. All steps will be taken to ensure that such waste is handled without any adverse effect to human health and environment.

9.(1) *An establishment of Optical Center shall have the following criteria:*

(a) Personnel

The Optical Center should be under the supervision of an Ophthalmologist with a degree from a recognized University or an Ophthalmic Assistant with a degree from a recognized University or a person with Diploma in Optometry from a recognized University. The Ophthalmic Assistants and Optometrists desiring to practice Contact Lens should obtain qualification certificate of the same from a recognized University.

(b) Equipments

All the Optical Centers shall have the following essential instruments:-

(i) Lensometer
(ii) Trial Lens set
(iii) Optician Ruler
(iv) Cross Cylinder

(c) General Terms and Conditions

(i) Persons with requisite qualification recognized by the All India Council of Technical Education only will be issued with registration of Optical Center and license to practice.

(ii) All applicants except Ophthalmologist shall be screened by the designated Ophthalmologist of S.T.N.M. Hospital prior to issue of registration and license.

(iii) Persons (Ophthalmic Assistants and Optometrists) shall take prior permission of the authorities in case of using Auto Refractometers and Computerized Eye Testing Centers.

(iv) All signboards, hoardings for the Optical shop run by an Optometrist or Ophthalmic Assistant shall bear the name of the shop only and nothing else."

By Order and in the name of the Governor

Dr. T. R. Gyatso
Secretary to the Government of Sikkim
Department of Health Care, Human Service and Family Welfare

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